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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,988	12/09/2005	Won-Bong Park	0056986-000004	6539

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
06/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/559,988	PARK ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5* is/are pending in the application.

4a) Of the above claim(s) *5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed April 14, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Drawings

1. The replacement drawings were received on April 14, 2009. These drawings are acceptable.

Specification

2. The disclosure is objected to because of an improper incorporation by reference. The attempt to incorporate subject matter into this application by reference to KR 2000-83383 and KR 2001-0061118 is ineffective because essential subject matter cannot be incorporated by reference to a foreign application or patent. Appropriate correction is required.

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection,

rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Claim Rejections - 35 USC § 112 – 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. Applicants have not provided written description to provide one skilled in the art the methodology by which the mistletoe lectin extract and zein protein extract are prepared. Based on the varieties of mistletoe, the portion(s) of the plant which are extracted and the conditions under which the extract is obtained (time, temperature, solvent(s), etc.), the mistletoe lectin extract being claimed is not sufficiently described to convey to one skilled in the art that

applicant had possession of all the extracts encompassed by "mistletoe lectin extract". In regards to the "zein protein extract", a similar lack of information regarding the process under which such an extract is prepared, renders "zein protein extract" insufficiently described as required by the 35 USC 112, first paragraph.

5. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The originally filed disclosure indicates that ZEIN®-DP is an extract of corn protein. However, the originally filed disclosure does not provide support for a further extract of zein as now recited in the instant claims.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The form of the pharmaceutical formulation being claimed is unclear. As now recited, the formulation contains lectin and three different solutions

(binder, first coating and second coating). It remains unclear if applicant is claiming the various separate solutions prior to preparation into a dosage from, such as might be encountered in a manufacturing facility, or a formulation in which lectin is mixed with the binder solution, first coating solution and second coating solution to produce a solid dosage form with multiple coatings applied to it. Please clarify.

Response to Arguments

8. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection presented below.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruepp et al. (DE 19639375; all citations from machine translation) in view of Margolin et al. (US 2002/0045582), Cook (US 5,567,438) and Green (US 4,026,851).

Ruepp et al. discloses the use of dry extracts of mistletoe in oral pharmaceuticals (p 1, ¶ 1), and lectins are one component of mistletoe (p 1, ¶ 2). Lectins are glucose binding proteins (p 1 of the instant specification). Where appropriate, the pills can be coated with shellac or cellulose acetate phthalate, which are enteric coatings as they delay release of the ingredient until the small intestine (p 3, ¶ 4). Various excipients can be included in the composition (p 3, ¶ 3).

Ruepp et al. does not disclose the use of the other ingredients as recited in claim 1.

Margolin et al. discloses compositions comprising protein or nucleic acid in a stabilized form (abstract). The protein can be combined with conventional controlled release excipients and enteric coatings applied (¶ [0237]). A variety of excipients can be included in the pharmaceutical dosage form, including methacrylic acid copolymers, shellac or zein as coating agent (¶ [0112]). Microcrystalline cellulose as a suspending and/or viscosity increasing agent (¶ [0146]), dibasic calcium phosphate as a diluent (¶ [0152]) and hydroxypropyl methyl cellulose as a binder (¶ [0150]) are among the excipients which can be added.

Cook discloses that shellac only dissolves in high titer alcohol or water (col 11, ln 27 – 29) and that a composite film made of zein and shellac exhibited better water barrier properties than a shellac only coating (col 11, ln 45 – 53). Inclusion of zein in the shellac coating allows for proper disintegration of the coating, regardless of any shellac aging that may occur (col 11, ln 53 – col 12, ln 4).

Green discloses that acid components such as triethyl acetic acid can be included as an acid catalyst in curing acrylate or alkyl methacrylate polymers (col 1, ln 9 – 11; col 2, ln 11 and ln 52).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a lectin containing dosage form, such as the mistletoe extract disclosed by Ruepp et al., and to include standard pharmaceutical excipients such as microcrystalline cellulose, dibasic calcium phosphate and HPMC in the tablet core and to provide the dosage form with an enteric coating, as disclosed by both Ruepp et al. and Margolin et al. Cook discloses that zein and shellac, only soluble in

high titer alcohols like ethanol, provides a water barrier coating layer whose properties are not effected by age, while an enteric coating layer comprised of methacrylic acid copolymers, mixed with triethyl acetic acid to improve the curing properties of this polymer layer, can also be applied to provide an enteric coating to the dosage form. The selection of excipients and the solvents in which the various excipients should be applied is part of routine dosage formulation by one of ordinary skill in the art. By the selection of the excipients and their amounts, parameters such as the stability of the dosage form over time and the desired release profile of the drug are determined and therefore are result effective parameters. Such parameters are routinely optimized by a person of ordinary skill in the art. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal ingredients and amounts of those ingredients to add in order to best achieve the desired results.

The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 If an applicant contends that additional

steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) **MPEP 2111.03** The components of the pharmaceutical composition are not limited because no definition of "consisting essentially of" has been provided and the preamble of the claim uses the completely open language of comprising.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW